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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,288	01/09/2001	Signe Uhre Guldfeldt	P66317US0	5968

136 7590 12/18/2002

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/756,288

Applicant(s)

GULDFELDT ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 7.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 at line 3, claim 5 recites the limitation “leaves” which based upon the context of the rest of the claim, appears to have intended to be another term, and is given no support in the specification.

Claim 15 provides for the use of an external urinary catheter, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

Art Unit: 3761

process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

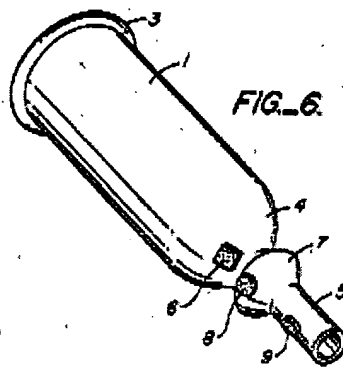
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 8, and 10-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fajnsztajn (US 4,656,675) in view of Blanton (US 6,165,159)..

Regarding claim 1, Fajnsztajn teaches an external urinary catheter device (1) for the relief of male urinary incontinence, comprising a contact member (4) which is adapted to be engaged with at least the extreme portion of a penis, an opening formed in a distal end section of the

Art Unit: 3761

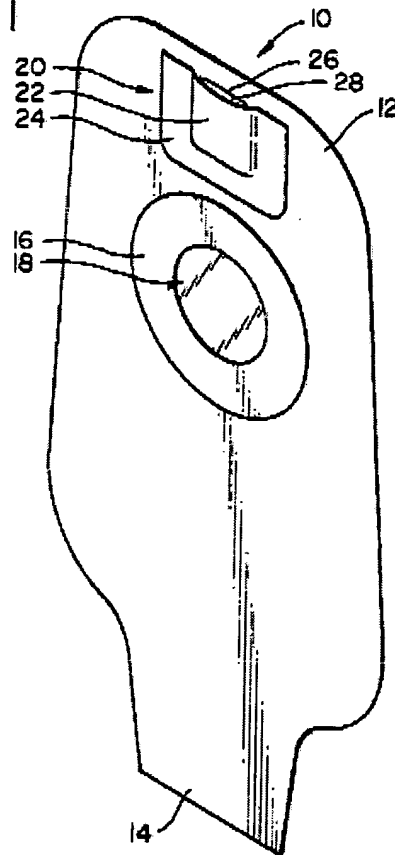
contact member (4) and positioned substantially opposite the urethral orifice in the position of use, a discharge conduit (5) connected with the opening to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device (1), wherein, an aperture (6) is provided in a distal part of the contact member (4) or in the discharge conduit (5), a membrane (6) is fastened to the surface surrounding said aperture (6), the membrane (6) being capable of selectively passing gases but retaining urine (*see* Fig. 6, below).



Fajnsztajn therefore expressly teaches every element of the claimed invention except for a shield to protect the membrane.

Blanton teaches an ostomy pouch which features a vent (42) covered by a membrane (60) which is protected by a shield (22)(*see* Fig. 1, below).

FIG. 1



At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the shield of <sup>Blanton</sup> ~~Leide, Jr.~~ with the urinary drainage device of Fajnsztajn in order to provide a means of protecting and holding the membrane in place.

Regarding claim 2, Fajnsztajn teaches a contact member (4) integrally connected with discharge conduit via the opening formed in the distal end section of the contact member (4).

Regarding method claims 7, 8 and 10-13 it is noted that applicants have expressly stated that they are not patentably distinct from the above rejected apparatus claims

Regarding claim 14, Fajnsztajn teaches a kit for relief of male urinary incontinence comprising an external urinary catheter device comprising a bag for collection of urine

Art Unit: 3761

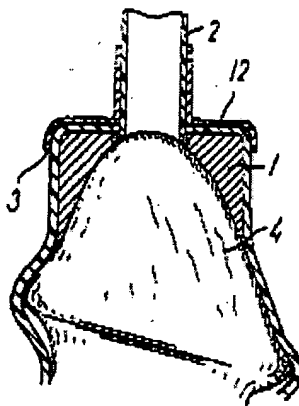
discharged from the catheter device (1), and a hose member (5) connecting the catheter device (1) and the bag (col. 2, lines 15-17).

Regarding claim 15 Fajnsztajn teaches the use of a external urinary catheter device for relief of male urinary incontinence (Abstract).

Claims 3, 4, 6 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fajnsztajn and Blanton as applied to claims 1, 2, 7, 8, 14 and 15 above, and further in view of Tanghøj (US 5,685,870).

Regarding claim 3, Fajnsztajn and Blanton expressly teach every element of the claimed invention except for an inner member.

Tanghøj teaches a contact member (1) which is an inner member arrangeable, in a position of use, between the foreskin and the corona of a penis (*see* Fig. 3, below).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the vent of Fajnsztajn and Blanton with the device as taught by Tanghøj in order to provide venting and increased comfort.

Art Unit: 3761

Regarding claim 4, Tanghøj teaches a inner member (1) which comprises a shoulder-like ledge at a substantially plane abutment face of the contact member around and substantially perpendicular to the discharge conduit (2).

Regarding claim 6, Tanghøj further teaches an outer holder member (12) for fastening the contact member (1) in the position of use, wherein the outer holder member (12) is formed in a distal end section with an opening for said discharge conduit (2) and arrangeable in said position of use, in a substantially fixed axial position with respect to the discharge conduit for circumferential engagement with the external side of the foreskin (3).

Regarding method claim 9, it is noted that applicants have expressly stated that they are not patentably distinct from the above rejected apparatus claims

Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fajnsztajn, Blanton and Tanghøj as applied to claims 3, 5 and 6-13 above, and further in view of Wendler (US 5,211,640).

Fajnsztajn, Blanton and Tanghøj expressly teach the claimed invention except for an adhesive.

Tanghøj teaches an adhesive layer (7) on the interior surface thereof to secure an attachment of the device to the corona of a penis.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the adhesive of Wendler with the device as taught by Fajnsztajn, Blanton and Tanghøj in order to provide a more secure attachment of the device when in use.



Art Unit: 3761


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, Weilun Lo may be reached at phone number (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 306-4520 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.

  
Michael Bogart  
December 12, 2002

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700